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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,089	08/21/2003	Marcel Behr	STAN-102CON2	1719

24353 7590 03/29/2005

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EXAMINER
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LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/647,089

Applicant(s)

BEHR ET AL

Examiner

Gerald G. Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-18 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-18 and 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/21/2003
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group D (claims 16-18; open reading frame Rv2653a described by SEQ ID NO: 93) in the reply filed on 12/15/2004 is acknowledged. Receipt is also acknowledged of an amendment, filed 12/15/2004, in which claims 1-15, 19-23 were cancelled and in which new claims 24-28 were added. Claims 16-18, 24-28 are pending and under consideration in the instant application.

### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application (U.S. Provisional Application No. 60/097,936) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 16-18, 24-28 of this application. Specifically, there is no description of open reading frame Rv2653c in the provisional application. Accordingly, the instant claims are only given priority to the filing date of the parental application, U.S. Application Serial No. 09/318,191, which is 5/25/1999.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 16-18, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US 2004/0013685 A1; see the entire application).

Anderson et al teach nucleic acid fragments and polypeptide fragments derived from *M. tuberculosis* (Mtb) that are useful for diagnosis of whether a subject has been exposed to *M. tuberculosis* (e.g. Abstract). In particular, Anderson et al characterize the immunogenic properties of polypeptide fragments encoded by *M. tuberculosis* open reading frame Rv2653c with regard to stimulation of antigen-specific T-cell and antibody responses from individuals exposed to Mtb (e.g. Example 10; Example 12). Anderson et al teach that with regard to ability to induce the release of interferon  $\gamma$  from the T cells of different subjects, peptides derived from Rv2653c resulted in a marked release of IFN- $\gamma$  from TB patients whereas none of the peptide fragments resulted in IFN- $\gamma$  release from BCG vaccinated healthy individuals, indicating that Rv2653c polypeptides are ideal candidates for discriminating between TB infected and BCG infected individuals (paragraphs 0207-0214). Anderson et al further teach that in *in vitro* assays, purified protein expressed from cloned Rv2653c reacted to sera obtained from TB patients but not with sera obtained from healthy, nonvaccinated individuals (e.g. Example 12, Table 15). In addition to exemplifying an *in vitro* assay, Anderson et al also teach that one can use the polypeptides of the invention in the well-known skin test to determine the subject's exposure to Mtb (e.g. paragraph 01410).

Anderson et al claim priority to U.S. Serial Application No. 09/246,191 (filed 12/30/1998) and U.S. Provisional Application No. 60/070,488 (filed 6/14/2001), both of which antedate the priority date for the instant claims.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (US 2004/0013685 A1; see the entire application) in view of Haslov et al (U.S. Patent No. 6,120,776 A; see the entire patent).

The teachings of the Anderson et al application are described above and are applied as before, except:

Anderson et al do not teach that the sub-cutaneous injection of the protein derived from Rv2653c necessarily comprises 0.05-5 ug of protein.

Haslov et al teach a diagnostic skin test for determination of exposure to different Mycobacteria, including Mycobacterium tuberculosis (e.g. Abstract). Haslove et al teach at least

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one example where purified recombinant protein (rMPT64) is used at 0.1 ug for a skin test in the guinea pig animal model (e.g. Example 6).

It would have been obvious to one of ordinary skill in the art to optimize the level of recombinant protein derived from Rv2653c to a level that falls within the range recited in claim 24 because optimization is routine in the art for diagnostic assays and because Haslov et al demonstrate with a different recombinant Mtb protein that even a small amount of protein can elicit a detectable response in an Mtb skin test (i.e. sub-cutaneous injection). One would have been motivated to optimize the method for detecting Mtb using Rv2653c polypeptides in order to determine the recombinant protein concentration that yields a detectable response in most individuals that have been exposed to Mtb. Absent any evidence to the contrary, there would have been a reasonable expectation of success in using amounts of recombinant Rv2653c-derived protein similar to those amounts described by Haslov for rMPT64 in the diagnostic assays taught by Anderson et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

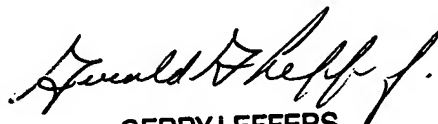
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER